



6-21-04

IFW

Patent Application  
Attorney Docket No. PC25240A

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: Mail Stop Amendments, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on this 18th day of June, 2004.

By

*Kelly A. Smith*  
(Signature of person mailing)

Kelly A. Smith

(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Timothy A. Hagen, et al. :

APPLICATION NO.: 10/763,340 : Examiner:

FILING DATE: January 23, 2004 : Group Art Unit: 1615

TITLE: AZITHROMYCIN DOSAGE FORMS WITH :  
REDUCED SIDE EFFECTS

Hon. Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 C.F.R. § 1.97 ET SEQ.

Applicant(s) herein make(s) available to the U.S. Patent and Trademark Office a copy of PTO-FB-A820 which lists the references cited by the applicant(s), copies of which are enclosed.

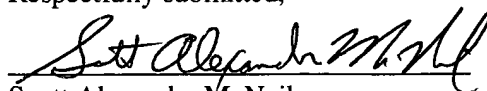
The Examiner is requested to consider carefully the complete text of these references in connection with the examination of the above-identified application in accord with 37 C.F.R. § 1.104(a). It is believed the Examiner will concur with applicant's belief that the subject matter presently claimed is neither anticipated nor rendered obvious by the foregoing references.

It is requested that the references listed on the attached form PTO-FB-A820 be included in the "References Cited" portion of any patent issuing from this application (M.P.E.P. § 1302.12).

A prompt and favorable response is earnestly solicited.

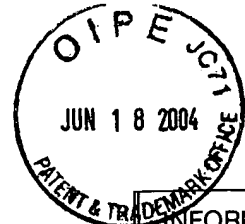
Date: 18 June 2004

Respectfully submitted,



Scott Alexander McNeil  
Attorney for Applicant(s)  
Reg. No. 37,185

Pfizer Inc.  
Patent Department, MS 8260-1611  
Eastern Point Road  
Groton, Connecticut 06340  
(860) 686-1848



INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	ATTY. DOCKET NO. PC25240A	SERIAL NO. 10/763,340
	APPLICANT Timothy A. Hagen, et al.	
	FILING DATE January 23, 2004	GROUP 1615

### U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	US	5	1	6	9	6	4	5	12/8/92	Shukla, et al.	424	499	
	US	5	6	3	3	0	0	6	5/27/97	Catania, et al.	424	441	
	US	5	6	0	5	8	8	9	2/25/97	Curatolo, et al.	514	29	
	US	5	7	0	5	1	9	0	1/6/98	Broad, et al.	424	465	
	US	5	7	4	7	0	5	8	5/5/98	Tipton, et al.	424	423	
	US	6	0	6	8	8	5	9	5/30/00	Curatolo, et al.	424	490	
	US	6	2	4	8	3	6	3	6/19/01	Patel, et al.	424	497	
	US	6	5	0	0	4	5	9	12/31/02	Chhabra, et al.	424	474	
	US	6	5	6	9	4	6	3	5/27/03	Patel, et al.	424	497	
	US	6	5	7	6	2	5	8	6/10/03	Kofler, et al.	424	458	
	US	6	6	8	2	7	5	9	1/27/04	Lim, et al.	424	468	
	US	6	6	9	2	7	6	7	2/17/04	Burnside, et al.	424	489	

### FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER									DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
									m/d/y				YES	NO
	WO	9	5	0	9	6	0	1	4/13/95	International	A61K	7/16		
	WO	9	8	1	8	6	1	0	5/7/98	International	B29C	47/04		
	WO	9	8	5	6	3	5	7	12/17/98	International	A61K	9/20		
	WO	0	3	1	8	0	3	1	3/6/03	International	A61K	31/7052		
	WO	0	3	3	7	3	0	4	5/8/03	International	A61K	9/16		
	WO	0	3	5	3	4	0	2	7/3/03	International	A61K	9/00		
	WO	0	3	6	3	8	3	4	8/7/03	International	A61K	9/16		
	WO	0	4	0	0	8	6	5	12/31/03	International	A61K	31/7048		

### OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Curatolo, et al., US Patent Application Publication No. US 2002/0009433, Application No. 09/788,886, Published 1/24/02
		Dunne, U.S. Patent Application Publication No. US 2004/0023898, Application No. 10/628,102, Published 2/5/04

EXPRESS MAIL NO. EV271824289 US.



INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)			ATTY. DOCKET NO. PC25240A	SERIAL NO. 10/763,340
			APPLICANT Timothy A. Hagen, et al.	
			FILING DATE January 23, 2004	GROUP 1615
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>				
			Foulds, G., et al., "The effects of an antacid or cimetidine on the serum concentrations of azithromycin", J. Clin. Pharmacol. 1991 Feb; 31(2): 164-7 (Abstract)	
			Amsden, G.W., et al., "Serum and WBC pharmacokinetics of 1500 mg of azithromycin when given either as a single dose or over a 3 day period in healthy volunteers", J. Antimicrobial Chemotherapy (2001), 47(1), 61-66 (Abstract)	
			Zithromax® azithromycin tablet 250 mg, Quantitative Composition of the Tablet Blend	
			Zithromax® azithromycin for oral suspension composition 200 mg/5mL, 200mg/5mL Drug Product	
			Zithromax® azithromycin for oral suspension composition 1 gram sachet, Quantitative Composition of the Drug Product	
			Zithromax® azithromycin for oral suspension composition 100 mg/5mL, Quantitative Compositions of the Drug Products	
			Zithromax® (azithromycin tablets and azithromycin for oral suspension), Full U.S. Prescribing Information, 70-5179-00-4	
			Zithromax® (azithromycin capsules) (azithromycin tablets) and (azithromycin for oral suspension), Full U.S. Prescribing Information, 69-4763-00-9	
			Food and Drug Administration Center for Drug Evaluation and Research Approved Drug Products with Therapeutic Evaluations, 24 <sup>th</sup> Edition, Orange Book Listings of Azithromycin Dosage Forms	
EXAMINER			DATE CONSIDERED	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.				

Conforms with FORM PTO-FB-A820

INFORMATION DISCLOSURE

EXPRESS MAIL NO. EV271824289 US